K131682

510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 12/04/2013

1. Applicant / Submitter

MEDIMECCA Co., Ltd.
Daeryung Techno Twon 3-cha 104~105, 448, Gasan-dong, Guemcheon-gu,
Seoul, 153-772 Rep. of Korea

Tel : +82-2-856-8282
Fax : +82-2-856-0238
Contact: Woo-young Ha

DEC 0 5 2013

2. U.S Agent/Submission Correspondent

LK Consulting Group USA, Inc.
1515 E Katellà Ave. Unit 2115, Anaheim, CA 92805
Priscilla Chung
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

Proprietary/Trade Name	UD Implant System
Common/Usual Name	Dental Implant
Classification Name	Endosseous Dental Implant
Classification Product Code	DZE, NHA
Classification regulation	21CFR872.3640
Class	II

4. Predicate Device:

Hero II and IS Dental Implant System by KJ Meditech Co., Ltd. (K121047)

5. Description:

UD Implant System is a dental implant system made of titanium (Fixture: ASTM F136 / Prosthetic Abutment: ASTM F136, ASTM F67 Gr 4) intend to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. This device may be used to replace one or more missing teeth. Its material, structure and intended use are substantial equivalence with the predicate device.

6. Model List

(1) Fixture

Diameter : Ø 3.75mm, Ø 4.0mm, Ø 4.5mm, Ø 5.0mm, Ø 6.0mm
Length : 7.3mm, 8.5mm, 10.0mm, 11.5mm, 13mm

*7.3mm length is not available for the 3.75 diameter implant fixtures.

(2) Abutments

No	Component	Description	
1	Cover Screw	Type	Internal
		Size(Diameter)	2.8mm, 3.37mm
2	Healing Abutment	Type	Internal
		Size(Diameter)	4.0mm, 4.5mm, 5.5mm, 6.5mm
3	Dual Abutment	Type	Internal Hex, Internal Non-Hex
		Size(Diameter)	4.0mm, 4.5mm, 5.5mm, 6.5mm
4	Combi Abutment	Type	Internal
		Size(Diameter)	4.0mm, 4.5mm, 5.5mm, 6.5mm
5	Angled Abutment	Type	Internal Hex, Internal Non-Hex Angle: 15°, 25°
		Size(Diameter)	4.5mm, 5.5mm
6	Milling Abutment	Type	Internal Hex, Internal Non-Hex
		Size(Diameter)	4.0mm, 4.5mm, 5.5mm, 6.5mm
7	Temporary Abutment	Type	Internal Hex, Internal Non-Hex
		Size(Diameter)	4.0mm, 4.5mm
8	Ball Abutment	Type	Internal Hex, Internal Non-Hex
		Size(Diameter)	3.5mm

7. Indication for use:

UD Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. UD Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.

8. Basis for Substantial Equivalence

The UD Implant System is substantially equivalent to previously marketed devices. The design features and sizing of the components were compared and the UD Implant System found to be substantially the same as the predicate device. It is indicated for the same intended use. There are no significant differences between the UD Implant System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to other devices in design, function, material and intended use.

Device Name	UD Implant System	HERO II Dental Implant System IS Dental Implant System
510(k) no	-	K121047
Applicant	MEDIMECCA CO LTD	KJ Meditech Company, Limited.
Classification	Endosseous dental implant (Class II, 21CFR872.3640)	Endosseous dental implant (Class II, 21CFR872.3640)
Material	Titanium (ASTM F136, ASTM F67 Gr 4)	Titanium 6Al 4V ELI Alloy
Surgery Type	One stage, Two stages	One stage, Two stages
Structure	Internal Hexagon connection Self-taping cutting edge threads	Internal Hexagon connection Self-taping cutting edge threads
Dimension	Fixture: Diameter : Ø 3.75mm, Ø 4.0mm, Ø 4.5mm, Ø 5.0mm, Ø 6.0mm Length : 7.3mm, 8.5mm, 10.0mm, 11.5mm, 13mm	Fixture: Diameter : Ø 3.75mm, Ø 4.0mm, Ø 4.5mm, Ø 5.0mm, Ø 6.0mm Length : 7.3mm, 8.5mm, 10.0mm, 11.5mm, 13mm
	Abutment Diameter : Ø 4~6.5mm	Abutment Diameter : Ø 4~7mm
Surface(Fixture)	R.B.M.	R.B.M.
Intended use	intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. UD Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.	intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. HERO II Dental Implant System and IS Dental Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.
Sterilization	Gamma radiation	Gamma radiation
Shelf-life	5 years	5 years

9. Non-clinical Testing

The following non-clinical testing was conducted to validate its safety.

- Physical tests including visual test, packaging test, packaging seal efficacy test, dimension test, and sterility test (direct transfer method)
- Surface treatment tests including roughness average test, developed surface area ration test, surface characteristics test (SEM), and surface composition analysis test (EDX)
- Mechanical properties test including adaptation accuracy test (Implant to abutment compatibility), 35° compressive loads test, torsional breaking force test, removal torque force test, and fatigue test
- Sterilization validation and shelf life tests
- The biocompatibility tests have been performed in accordance with ISO10993 series.

10. Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of the titanium alloys and have the same surface treatments. The subject and the predicate devices encompass the similar range of physical dimensions, including diameter and length of the implants, and diameter of the abutments.

Overall, the UD Implant System has the following similarities to the predicate device:
* has the same intended use,
* uses the same operating principle,
* incorporates the same basic design,
* incorporates the same material and the surface treatment.

Based on the similarities, we conclude that the UD Implant System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 5, 2013

MEDIMECCA Company, Limited
C/O Ms. Priscilla Chung
Regulatory Affairs Consulting
LK Consulting Group USA, Incorporated
1515 East Katella Avenue, Unit 2115
Anaheim, CA 92805

Re: K131682
Trade/Device Name: UD Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 4, 2013
Received: November 7, 2013

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131682

Device Name
UD Dental Implant System

Indications for Use *(Describe)*
UD Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. UD Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Susan Runner DDS, MA Mary S. Runner -S
2013.12.05 08:45:15 -05'00'